INTENT TO SUBMIT

The Intent to Submit process is designed to support you in submitting your funding application, and in planning your project. When you click “submit”, this form will route to your department and to the myRESEARCHnavigators team.

**PI Information**

1. Are you the PI for this project? **Yes / No**
2. Is the PI a first-time PI at Duke? **Yes / No**
3. Is the PI regular rank faculty, or if not, do they have PI status at Duke (see PI Eligibility policy)? **Yes / No**
4. What department should this proposal be routed through?

**Funding Application Information**

5. Project Title ________________________________
6. Sponsor/Funder ______________________________
7. Is this an industry-sponsored clinical trial? **Yes / No**
8. FOA Number or URL _____________________________
9. Which activity best describes this project (select one):
   - Research
   - Clinical Trial
   - Conference
   - Inst. Training Program or CME
   - Fellowship
   - Public Service
   - Institutional Support
   - Equipment
   - Construction/Renovation
10. Sponsor Due Date ______________________________
11. Planned submission date __________________________

**Project Activity Information**

12. Planned Project Start Date __________________________
13. How long is the project period?
   - 5 years
   - 4 years
   - 3 years
   - 2 years
14. How long is the first budget period for this project?
   - 1 year
   - Same length as the project period
   - Other
     - If other, list the end date for the first budget period

15. Draft study aims, goals, abstract or brief description of project

16. Does this application have potential similarities/overlap with other submitted or awarded research projects? [more info available here]: Yes / No / Unsure
   - If YES, describe the potential similarities or scientific overlap

17. To make sure we are prepared to assist with deadlines, required documents, and complex situations, please mark which of the following conditions apply
   - The study has multiple PIs: Yes / No / Unsure
   - Duke subaward(s) to another organization: Yes / No / Unsure
     - If YES, approximately how many (1-3; 4-6; more than 7)
   - Duke as a Sub-Contract (i.e., Sub-Awardee): Yes / No / Unsure
   - Historical Site (i.e., Chesterfield Building): Yes / No / Unsure
   - Institutionally Limited submission requiring nomination: Yes / No / Unsure
   - In Kind/Cost Sharing (Not Including NIH Salary Cap): Yes / No / Unsure
   - VA involvement: Yes / No / Unsure
     - If YES, will any portion of the scope of work be completed by VA personnel, be done using VA facilities, or involve use of VA data? Yes / No / Unsure
   - Involves Human Subjects: Yes / No / Unsure
     - If YES, Will there be patient care costs? Yes / No / Unsure
   - Involves vertebrate animals: Yes / No / Unsure
   - Requires Institutional Biosafety Committee review: Yes / No / Unsure
   - Involves technologies, including using or developing mobile and web applications, websites, etc.: Yes / No / Unsure
     - If YES, briefly describe the technologies involved
• Will use existing internal/administrative Duke University or Duke Health data: Yes / No / Unsure
  o If YES, briefly describe the type of data that will be used

• Needs specialized storage and/or computing environments (e.g., sensitive/restricted data, patient data, proprietary data, large files, etc.): Yes / No / Unsure
  o If YES, briefly describe the computing needs

• Use of a Duke core facility, or other space/service/procedure provided by another department? (e.g., Regional Biocontainment Laboratory, shared resource, etc.): Yes / No / Unsure
  o If YES, briefly describe the facility, space, or resource

• Involves investigational drugs, biologics, devices, and/or tobacco products, which would include, for example, a completely novel product or an FDA-approved product off label: Yes / No / Unsure
  If YES, please mark if any of the following apply to this project:
  o Manufacturing of a medical product that will be administered to human subjects. This includes, but is not limited to, compounding of novel products, cellular therapies, and changes to an FDA-approved product.
  o Involves FDA Regulatory Affairs for “Commercial” Activities – to support an investigational application where the product under investigation is intended to be commercialized at a later date (ex. requires the submission of a commercial IND), an FDA marketing application (ex. 510(k) or BLA), or modification of an FDA-cleared/approved product (ex. label change).
  o Involves FDA Regulatory Affairs for Coordinating Center Role – to support large, multi-center studies or projects that require use of a coordinating center.
  o Involves FDA Regulatory Affairs for Multi-Project Programs – to support large, multi-project research activities, such as Program Project/Center Grants (P series), Cooperative Agreements (U01), or projects of similar magnitude.

• This study involves International Activities: Yes / No / Unsure
  • If YES, please mark which of the following apply to your work outside of the US
    o will use Duke funds to hire and directly pay local staff as contractors, employees, or casual day laborers
    o will open a local bank account
    o will buy or lease vehicles
    o will lease office or residential space
    o will engage in human subjects or animal activities
    o will engage in clinical trial(s)
    o will have Duke faculty, staff, or students spend significant time (i.e. > 4 mos per year) supporting the project outside the US
    o None of the above
  • If any of the above are selected (except ‘None’):
    o In what country or countries are you planning to conduct your research/activities?
    o In 2-3 sentences, briefly describe the activities that will take place outside of the US.
    o Have you identified a trusted in-country partner that can support the in-country activity you need? Yes / No
      • If YES, specify who:
18. Would you like a free 10-15 minute project planning consultation to ensure awareness of resources that can benefit your project? The consultation will be completed by an expert from the myRESEARCHnavigators team. This is supplemental to your departmental grants management team who will be automatically notified about this intent to submit. **Yes / No**